

REMARKS

The applicants have studied the Office Action dated January 13, 2005, and have made amendments to the application. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 1-13 and 89-91 are pending, claims 1, 4 and 6-9 have been amended and new claim 91 has been added. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

Support for new claim 91 can be found generally throughout the specification including page 21, line 19 – page 23, line 5. No new matter has been added.

Claims 1-13 and 89-90 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,360,888 to McIvor et al. This rejection is respectfully traversed.

Embodiments of the present invention are directed to a sensor with notches cut in the substrate to form a necked down region in the substrate and non-necked down region in the substrate adapted for placement within the body. The notches cut in the substrate are used for insertion of the sensor into the body of the patient and are specifically designed to avoid exposing the electrodes of the sensor. An example of the present invention is shown in FIG. 26 of the application which shows a sensor 400 with a notch 406 that creates a necked down region 412 and a non-necked down region 414 (page 22 lines 5-10). Amended claim 1 (and thus dependent claims 2-13 and 89-90) specifically recites: “[a] sensor for implantation in a body, the sensor comprising: a substrate with notches cut in the substrate to form a necked down region in the substrate and a non-necked down region in the substrate wherein the non-necked down region is adapted for placement within the body; and at least one sensor electrode formed from one or more conductive layers, wherein the notches cut in the substrate do not expose any sensor electrode to analytes” (emphasis added). The McIvor et al. reference does not describe a substrate with notches cut in the substrate that form a necked down region and a non-necked down region of the substrate adapted for placement within the body.

The McIvor et al. reference is primarily directed to a glucose sensor package system for storing and transporting a glucose sensor. To give context to the invention, the McIvor et al. reference only references a sensor in the written description, but only a sensor without notches cut in the substrate, as recited in the claims. The Examiner incorrectly concludes that the FIGS. 1-2 and 13-15 of the McIvor et al. reference teach the claimed invention. FIGS. 1-2 only show a subcutaneous glucose sensor insertion set coupled to a glucose monitor device. In these figures, the only view of the glucose sensor is a perspective view that does not reveal any notches cut in the substrate, as recited in the claims. Similarly, FIGS. 13-15 of the McIvor et al. reference do not show a substrate with notches cut in the substrate, as recited in the claims. FIGS. 13-15 show only a top plan view of the sensor with no notches cut in the substrate, as specified by the claims. Moreover, the written description of FIGS. 1-2 (col. 10) and FIGS. 13-15 (cols. 8-9) do not describe a sensor with notches cut in the substrate. Since FIGS. 1, 2 and 13-15 of the McIvor et al. reference do not show a sensor with notches cut in the substrate, the McIvor et al. reference does not anticipate the claimed subject matter.

Therefore, it is respectfully submitted that the rejection of claims 1-13 and 89-90 under 35 U.S.C. § 102(e) should be withdrawn.

Claims 1-3 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,543,958 to Cartmell. This rejection is respectfully traversed.

The Cartmell reference generally describes dispensable medical electrodes formed from separable segments of an indefinitely long substrate. More specifically, the Cartmell reference discloses a method of applying a conductive tape to a substrate made of integrally formed electrode segments partially separated by weakenings which allow individual electrode segments to be severed from the indefinitely long substrate and attached to the skin of a patient. The Cartmell reference does not, however, disclose, teach or suggest an analyte sensor for implantation in a body where a non-necked down region in the substrate is adapted for placement within the body, as recited in the claims. Instead, the medical electrodes described in the Cartmell reference are “affixed to the skin of the subject or patient for purposes of exchanging electrical signals between the skin of the patient and the peripheral equipment” (col. 2 lines 55-

60). Further, the only use of the medical electrodes disclosed, taught or suggested by the Cartmell reference is for direct attachment the skin of the patient (see col. 1 line 15, col. 1 line 40, col. 2 lines 55-60, col. 4 lines 10-13, col. 4 line 37-40, col. 6 line 1, col. 6 line 38, col. 7 line 60, col. 8 line 7, col. 8 line 26, col. 8 line 34, and col. 9 lines 24-28). Nowhere in the Cartmell reference describes the use of medical electrodes for implantation in a body, as recited in the claims. Since the Cartmell reference does not disclose, teach or suggest an analyte sensor for implantation in a body where a non-necked down region in the substrate is adapted for placement within the body, the Cartmell reference does not anticipate the claimed subject matter.

Therefore, it is respectfully submitted that the rejection of claims 1-3 under 35 U.S.C. § 102(b) should be withdrawn.

Claims 1-13 and 89-90 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,390,671 to Lord et al. This rejection is respectfully traversed.

The Lord et al. reference generally describes a transcutaneous sensor insertion set used to place a sensor at a selected site within the body of a patient. The sensor of the Lord et al. reference includes a proximal end and a distal end which are linearly offset or misaligned. The Lord et al. reference does not, however, describe a substrate with notches cut in the substrate where the notches cut in the substrate form a non-necked down region in the substrate adapted for placement within the body, as recited in the claims (emphasis added). As shown in FIG. 8 of the Lord et al. reference, an offset transition segment 26 joins the sensor's proximal end 28 to the sensor's distal end 16. The offset transition segment of the Lord et al. reference does not, however, create a "non-necked down region" of the sensor adapted for placement within the body. Since the Lord et al. reference does not show a sensor with notches that creates a non-necked down region adapted for placement within the body, the Lord et al. reference does not anticipate the claimed subject matter.

Therefore, it is respectfully submitted that the rejection of claims 1-13 and 89-90 under 35 U.S.C. § 102(b) should be withdrawn.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Examination and consideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5003 should the Examiner believe a telephone interview would advance the prosecution of the application.

Respectfully submitted,

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